

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH
and BIOGEN MA INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,
et al.,

Defendants.

C.A. No. 17-823-LPS
(Consolidated)

(C.A. No. 17-855-LPS)

(C.A. No. 19-211-LPS)

STIPULATION AND ORDER OF PARTIAL DISMISSAL
Biogen International GmbH, et al. v. Hetero USA Inc.

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, “Biogen” or “Plaintiffs”) brought the following action against defendants Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited (“Hetero” or “Defendant”), alleging infringement of U.S. Patent Nos. 6,509,376 (“the ’376 patent”), 7,320,999 (“the ’999 patent”), and 8,399,514 (“the ’514 patent”) by submission of Hetero’s Abbreviated New Drug Application (“ANDA”) No. 210500: *Biogen International GmbH, et al. v. Hetero USA Inc.*, No. 1:17-cv-855-LPS, filed June 26, 2017 (“the 17-855 Action”). The Court later consolidated this action with *Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-823-LPS (the “Dimethyl Fumarate Consolidated Action”).

Biogen then brought the following action against Hetero alleging infringement of U.S. Patent No. 7,619,001 (“the ’001 patent”) by submission of Hetero’s ANDA No. 210500: *Biogen International GmbH, et al. v. Hetero USA Inc. et al.*, No. 1:19-cv-211-LPS, filed January 1, 2019 (“the 19-211 Action”). The Court later consolidated this action with the Dimethyl Fumarate Consolidated Action.

Biogen and Hetero stipulate to a dismissal of the 19-211 Action in accordance with the terms and conditions as set forth herein.

IT IS HEREBY STIPULATED, subject to the approval of the Court:

1. Hetero hereby stipulates and covenants for itself and its successors-in-interest to ANDA No. 210500 to not launch the dimethyl fumarate delayed-release capsules containing 120 mg and 240 mg of dimethyl fumarate as described in ANDA No. 210500 (“Hetero’s ANDA Product”) prior to the expiration of the ’001 patent, *i.e.*, June 20, 2020.

2. All claims, defenses, and counterclaims regarding the ’001 patent brought in C.A. No. 19-211 are dismissed without prejudice.

3. A statutory stay of FDA approval of Hetero’s ANDA No. 210500 is currently in effect pursuant to the Hatch-Waxman Act, and the dismissal of the 19-211 Action shall have no effect on this statutory stay of FDA approval imposed under the Hatch Waxman Act.

4. Any Judgment entered in the Dimethyl Fumarate Consolidated Action concerning willful infringement, enhanced damages under 35 U.S.C. § 284, exceptional case under 35 U.S.C. § 285 or costs under 28 U.S.C. § 1920 shall not be entered in the 19-211 Action. Both parties have agreed to waive any claim for attorneys’ fees and/or costs against the other in the 19-211 Action.

5. The obligations imposed on Biogen and Hetero by this Stipulation shall be binding upon Biogen and Hetero and their respective parents, subsidiaries, affiliates and successors, including any successor-in-interest to Hetero’s ANDA No. 210500.

6. This Stipulation grants no rights to Hetero under any patents or other proprietary rights.

ASHBY & GEDDES

BAYARD, P.A.

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-188
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

*Attorneys for Plaintiffs/Counterclaim
Defendants Biogen International GmbH and
Biogen MA Inc.*

Of counsel:

James B. Monroe
Li Feng
Paul Browning
Andrew E. Renison
Jeanette M. Roorda
John E. Nappi
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

/s/ Stephen B. Brauerman

Stephen B. Brauerman (#4952)
600 N. King Street, Suite 400
Wilmington, DE 19801
(302) 655- 5000
sbrauerman@bayardlaw.com

*Attorneys for Defendants/Counterclaim
Plaintiffs Hetero USA Inc., Hetero Labs
Limited Unit-III, and Hetero Labs Limited*

Of counsel:

Todd Werner
Saukshmya Trichi
CARLSON, CASPERS, VANDENBURGH,
LINDQUIST & SCHUMAN, P.A.
225 South Sixth Street, Suite 4200
Minneapolis, MN 55402
(612) 436-9600
twerner@carlsoncaspers.com
strichi@carlsoncaspers.com

Dated: October 11, 2019

SO ORDERED this _____ day of _____, 2019.

Chief Judge